

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

To:

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(day/month/year) 23 JUNE 2004 (23.06.2004)

Applicant's or agent's file reference  
YL04003PCT

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/KR2004/000606**

International filing date (day/month/year)

**19 MARCH 2004 (19.03.2004)**

Priority date(day/month/year)

**12 JUNE 2003 (12.06.2003)**

International Patent Classification (IPC) or both national classification and IPC

**IPC7 A61K 9/50**

Applicant

**PARK, Won-Bong et al**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.  
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



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**WRITTEN OPINION OF THE  
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International application No.

PCT/KR2004/000606

**Box No. 1 Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1-5	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-5	NO
Industrial applicability (IA)	Claims	1-5	YES
	Claims		NO

**2. Citations and explanations :**

D1 = WO 98/13053 (02.04.1998)

D2 = US 6046177 (04.04.2000)

D3 = US 5565200 (15.10.1996)

Claims 1-5 of the present invention relate to a composition for an enteric coating of a natural product containing lectin including an additive, bonding liquid and coating liquid.

D1 relates to an enteric coating tablet containing mistel(viscum) which is coated with shellac, CAP and cellulose derivatives and relates to a capsule.

D2 describes an enteric coating tablet or a capsule which can contain plant extract including a granulation process using Avicel, dibasic-calcium phosphate, mannitol, sucrose and starch, and a coating process using HPMC, HPMCP, shellac, alginates and gums.

D3 discloses that Korean mistletoe extract is useful as a treatment for cancer and immune diseases.

Claims of the present invention with the above cited documents are compared below.

**1. Novelty**

Claims 1-5 of the present invention provide enteric coating composition containing lectin; therefore, they have the same purpose of D1. In the technical component, compared to D1, the present invention which discloses an additive and a bonding liquid using a granulation process is not specifically described in D1. In addition, there is a difference in the feature that the present invention limits the kind of coating liquid and amount of composites respectively for enteric coating. D2 discloses a plant extract comprehensively without describing a natural product including lectin. D3 does not disclose a concrete description regarding the technical component of an enteric coating. Therefore, the above claims are considered to be novel over D1-D3 (PCT Article 33(2)).

(Continued on Supplemental Sheet)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of :

Box V.

2. Inventive Step

Claims 1-5 of the present invention are the same as D1 in using shellac, CAP and cellulose derivatives as an enteric coating material for the enteric coating composition containing mistel. There are differences in that the kinds of additives and bonding liquids used in the grannulation process and coating liquids used in a coating process which have been added, the amount is limited specifically, and a natural product including lectin except mistel.

The kinds of additives, bonding liquids and coating liquids are selected and combined from general components used in the grannulation process and coating process of D2. The limitation of the amount concretely can be selected by a skilled person by repeated experiments. and more, the critical effect by the limitation of the amount cannot be confirmed. A natural product including lectin other than mistel, has the same effect as lectin which is described in D3; therefore, there is no difficulty in selecting components.

In addition, the obvious enteric coating effect of the present invention which a skilled person cannot expect cannot be identified; therefore, Claims 1-5 of the present invention are not considered to involve an inventive step by D1-D3 [PCT Article 33(3)].

3. Industrial Applicability

Claims 1-5 of the present invention are considered to be industrially applicable [PCT Article 33(4)].